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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/610,313 07/05/00 BARNETT

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027476  
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INTELLECTUAL PROPERTY - R440  
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HM12/0713

EXAMINER

WHITEMAN, R

ART UNIT

PAPER NUMBER

1633  
DATE MAILED:

07/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/610,313

Applicant(s)

BARNETT ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Claims 1-47 are pending and under consideration in the instant application.

#### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-40 and 42-47, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Pol polypeptide, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented of Figure 8 (SEQ ID NO: 30); a recombinant expression system for use in a selected host cell, comprising, an expression cassette of claim 1; a composition for generating an immunological response, comprising an expression cassette of claim 1; a composition for generating an immune response, comprising an expression cassette of claim 2; a method of generating an immune response in a subject, comprising introducing into cells of said subject an expression cassette of claim 1, under conditions that permit the expression of said polynucleotide and production of said polypeptide, thereby eliciting an immune response to said polypeptide; a method of claim 29, wherein said expression cassette is introduced using a gene delivery vector; the expression vector of claim 1, further comprising one or more nucleic acids encoding one or more viral polypeptides or antigens, classifiable in class 435, subclass 320.1 and class 514, subclass 44.
- II. Claims 1-40 and 42-47, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Pol

polypeptide, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented of Figure 9 (SEQ ID NO: 31); a recombinant expression system for use in a selected host cell, comprising, an expression cassette of claim 1; a composition for generating an immunological response, comprising an expression cassette of claim 1; a composition for generating an immune response, comprising an expression cassette of claim 2; a method of generating an immune response in a subject, comprising introducing into cells of said subject an expression cassette of claim 1, under conditions that permit the expression of said polynucleotide and production of said polypeptide, thereby eliciting an immune response to said polypeptide; a method of claim 29, wherein said expression cassette is introduced using a gene delivery vector; the expression vector of claim 1, further comprising one or more nucleic acids encoding one or more viral polypeptides or antigens, classifiable in class 435, subclass 320.1 and class 514, subclass 44.

- III. Claims 1-40 and 42-47, drawn to an expression cassette comprising a polynucleotide sequence encoding a polypeptide including an HIV Pol polypeptide, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a sequence having at least 90% sequence identity to the sequence presented of Figure 10 (SEQ ID NO: 32); a recombinant expression system for use in a selected host cell, comprising, an expression cassette of claim 1; a composition for generating an immunological response, comprising an expression cassette of claim 1; a composition for generating an immune response, comprising

an expression cassette of claim 2; a method of generating an immune response in a subject, comprising introducing into cells of said subject an expression cassette of claim 1, under conditions that permit the expression of said polynucleotide and production of said polypeptide, thereby eliciting an immune response to said polypeptide; a method of claim 29, wherein said expression cassette is introduced using a gene delivery vector; the expression vector of claim 1, further comprising one or more nucleic acids encoding one or more viral polypeptides or antigens, classifiable in class 435, subclass 320.1 and class 514, subclass 44.

- IV. Claim 41, drawn to a method for generating an immune response in a subject, comprising: providing an expression cassette of claim 1 (SEQ ID NO: 30), expressing said polypeptide in a suitable host cell, isolating said polypeptide, and administering said polypeptide to the subject in an amount sufficient to elicit and immune response, classifiable in class 435, subclass 70.1 and 514, subclass 12.
- V. Claim 41, drawn to a method for generating an immune response in a subject, comprising: providing an expression cassette of claim 1 (SEQ ID NO: 31), expressing said polypeptide in a suitable host cell, isolating said polypeptide, and administering said polypeptide to the subject in an amount sufficient to elicit and immune response, classifiable in class 435, subclass 70.1 and 514, subclass 12.
- VI. Claim 41, drawn to a method for generating an immune response in a subject, comprising: providing an expression cassette of claim 1 (SEQ ID NO: 32), expressing said polypeptide in a suitable host cell, isolating said polypeptide, and

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administering said polypeptide to the subject in an amount sufficient to elicit and immune response, classifiable in class 435, subclass 70.1 and 514, subclass 12.

Claims 1-40 and 42-47 link(s) inventions I, II, and III. Claim 41 links inventions IV, V, and VI. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 1-40 and 42-47 or 41. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:

Inventions I and II, III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide sequence of invention I encodes Figure 8 (SEQ ID NO: 30) has a different function compared to the polynucleotide sequences of inventions II, III, which encode different

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polynucleotide sequences (SEQ ID NO: 31 or 32, respectively). Invention I requires different materials and the process for making the composition than in inventions II and III.

Inventions II and I, III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide sequence of invention II encodes of Figure 9 (SEQ ID NO: 31) has a different function compared to the polynucleotide sequences of inventions I, III, which encode different polynucleotide sequences (SEQ ID NO: 30 or 32, respectively). Invention II requires different materials and the process for making the composition than in inventions I and III.

Inventions III and I, II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide sequence of invention III encodes nucleotides of Figure 10 (SEQ ID NO: 32) has a different function compared to the polynucleotide sequences of inventions I, II, which encode different nucleotide sequences (SEQ ID NO: 30 or 31, respectively). Invention III requires different materials and the process for making the composition than in inventions I and II.

Inventions I-III and IV-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, inventions I-III use an expression cassette encoding either SEQ ID NO: 30, 31, or 32 for generating an immune response. Inventions IV-VI use the polypeptide

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produced from SEQ ID NO: 30, 31, or 32, respectively, to generate an immune response in a subject. Inventions I-III generate a completely different immune response than invention IV-VI.

As stated above, each of the inventions I-III has a distinct nucleotide sequence that is unrelated. The nucleotide sequences do not appear to share a common structure. Therefore, it would be an undue burden on the examiner to search all the nucleotide sequences, since each gene encodes a distinct functional polypeptide from different species and the USPTO resources are stretched to the limit. Thus, only one patentable distinct nucleotide sequence thereof can be searched per application.

As stated above, each of the inventions IV-VI has a distinct nucleotide sequence that is unrelated. The nucleotide sequences do not appear to share a common structure. Therefore, it would be an undue burden on the examiner to search all the nucleotide sequences, since each gene encodes a distinct functional polypeptide from different species and the USPTO resources are stretched to the limit. Thus, only one patentable distinct nucleotide sequence thereof can be searched per application.

Inventions IV and V, VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotide sequence of invention IV encodes Figure 8 (SEQ ID NO: 30) has a different function compared to the polynucleotide sequences of inventions V, VI, which encode different polynucleotide sequences (SEQ ID NO: 31 or 32, respectively). Invention IV requires different materials and the process for making the composition than in inventions V and VI.

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Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions I-VI constitutes patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above. The scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, none of the method steps cited in invention I-III use polypeptide therapy as claimed in invention IV-VI. Each of the inventions I-VI comprises materially distinct steps, and/or generates different functions and effects, and thus, is not required for use with one another.

This application contains claims directed to the following patentably distinct species of the claimed invention: mammalian cell of claims 9, 17, 19, 20, and 21, insect cell in claim 12, bacterial cell in claim 14, yeast cell in claim 15, and plant cell in claim 16.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 8 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775.

The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 746-5024.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Brian Whiteman  
Patent Examiner, Group 1633

July 8, 2001

to

BW 7/10/01

  
**DAVE T. NGUYEN**  
**PRIMARY EXAMINER**



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